UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,190	02/28/2002	Pia M. Challita-Eid	511582003420	7796

36327 7590 01/14/2008

AGENSYS C/O MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
01/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/087,190	CHALLITA-EID ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/21/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 October 2007 has been entered.

2. It is noted that the amendment filed 30 October 2007 omits claims 88-110, which were previously cancelled in the amendment filed 04 April 2007. Applicant is reminded that "Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application." See 37 CFR 1.121(c). Applicants' cooperation is requested in providing a complete listing of all claims ever presented in subsequent replies, particularly in the interest of preserving the original numbering of the claims.

3. Claims 1-82 and 84-110 are cancelled.

Claim 83 has been amended.

4. Claim 83 is under consideration to the extent that the transcript variant encodes the protein of SEQ ID NO:5, i.e., applicants' elected species.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. This office Action contains New Grounds of Rejections.

Information Disclosure Statement

7. The Information Disclosure Statements (IDS) filed 21 December 2007 has been fully considered. A signed and initialed copy of the IDS is included with this Office Action. It is noted that references 3 and 4 listed on the IDS filed 21 December 2007 lack a publication date and thus, are not true publications and not fully in compliance

with 37 CFR 1.98. While the contents of references 3 and 4 listed on the IDS filed 21 December 2007 have been fully considered by the examiner, references 3 and 4 have been lined-through on the IDS and will not appear on the face of a patent issuing from the instant application.

Rejections Maintained

8. The rejection of claim 83 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated 121P1F1 transcript or transcripts that encode the protein of SEQ ID NO:2, does not reasonably provide enablement for: (i) any isolated 121P1F1 transcript variant that encodes a protein comprising at least one amino acid substitution, addition or deletion relative to SEQ ID NO:2 *or the transcript variant of SEQ ID NO:5* is maintained.

The response filed 30 October 2007 notes that the U.S. patent and Trademark Office issued U.S. patent No. 6,924,358 ('358 patent) and has allowed USSN 11/125,805. USSN 11/125,805 is a continuation of the '358 patent and the present application claims priority to the '358 patent, and thus, is related to both the '358 patent and USSN 11/125,805. Applicant points out that the claims in the '358 patent are directed to an isolated protein encoded by SEQ ID NO:1 to the protein comprising SEQ ID NO:2 and which is useful as a diagnostic or therapeutic target on cancer cells. The claims in USSN 11/125,805 are directed to an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO:2, expression and viral vectors comprising the nucleic acid sequences and host cells comprising the expression vector. Applicant states that under 35 U.S.C. 282, the issuance of the parent case (the '358 patent) indicates that the protein sequence in question is presumed to possess the qualities of a useful and enabled invention. In view of the statutory imprimatur of validity for the protein of SEQ ID NO:2, it naturally flows that claims directed to protein variants that are immunologically reactive with at least one antibody that specifically binds the amino acid sequence of SEQ ID NO:2 enjoy the same patentable qualities of usefulness and

enablement of the parent case. Applicant asserts that the functional feature of the claimed protein is its ability to immunoreact with antibodies raised against SEQ ID NO:2. Applicant cites Lerner (Nature 299:592-596, 1982) as indicating that antibody epitopes can be as small as 6 to 15 amino acid residues long, which applicant asserts is evidence against the unpredictability of the protein of claim 1. Applicants' arguments have been fully considered but are not found persuasive. The examiner acknowledges applicants remarks regarding the parent gene product of US Patent 6,924,358 and USSN 11/125,805, however, it is noted that the 121P1F1 variants of USSN 09/799,250 (now US Patent 6,924,358) were rejected under enablement and lack of adequate written description under the first paragraph of 35 U.S.C. 112. Further, none of the 121P1F1 variants issued in the '358 patent and USSN 11/125,805 is not drawn to 121P1F1 variants.

Applicant also relies on the fact that there are homologous regions between SEQ ID NO:5 of the instant application and SEQ ID NO:2 and antibodies against SEQ ID NO:2 would cross-react with the transcript variant of SEQ ID NO:5 of the instant application and one skilled in the art could use the transcript variant of SEQ ID NO:5 to predictably provoke an immune response. Applicant is reminded that the enablement of 121P1F1 protein of SEQ ID NO:2 is based on the disclosure that SEQ ID NO:2 is encoded by the nucleotide sequence of SEQ ID NO:1 that is shown to be highly expressed in prostate cancer. Applicant has not disclosed an activity or biological function of the 121P1F1 protein of SEQ ID NO:2, or any variants thereof. Applicant has not taught how to make and use a transcript variant that encodes SEQ ID NO:5 because the instant application does not disclose the genus of transcript variants encoding SEQ ID NO:5 which share the function(s) and/or characteristic(s) of the 121P1F1 protein of SEQ ID NO:2, e.g., highly expressed in prostate cancer. The specification does not provide sufficient guidance as to which isolated 121P1F1-related protein (e.g., SEQ ID NO:5) would share the same function as the 121P1F1 protein of SEQ ID NO:2, if known. Neither does the specification provide any working examples of any 121P1F1-related protein (e.g., SEQ ID NO:5) that have the same functional activities or characteristics, i.e., highly expressed in prostate cancer as the 121P1F1

protein of SEQ ID NO:2. Further, while epitopes may be as small as 6-15 shared amino acids, such an epitope places no limitation on the function of the protein containing the polypeptide sequence recognized. For example, Bost et al (Immunol. Invest. 17(6 & 7):577-586, 1988) describe antibodies which "cross-react" with IL-2 and HIV envelope protein, and establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document, but especially the Abstract and Discussion). Similarly, Bendayan (The Journal of Histochemistry and Cytochemistry, 43(9):881-886, 1995) characterizes the specific reactivity of a monoclonal antibody produced to human proinsulin and shows that although the antibody is highly specific; it is nevertheless able to bind to not only human proinsulin, but to proinsulin from other species and even a distinct protein, glucagon, based upon conservation of an Arg-Arg dipeptide sequence in each of these molecules (see entire document). Bendayan concludes that "an antibody directed against such a sequence, although still yielding specific labeling, could reveal different molecules not related to the original antigen" (page 886, last paragraph). Thus, while the protein of SEQ ID NO:5 encoded by a transcript variant of SEQ ID NO:1 may share certain epitopes with the protein of SEQ ID NO:2, the instant application does not provide any guidance or direction to assist the skilled artisan in using an isolated transcript variant of SEQ ID NO:1 wherein the transcript variant encodes the protein of SEQ ID NO:5 because one skilled in the art could not extrapolate the characteristic of being overexpressed in prostate cancer to a transcript variant encoding SEQ ID NO:5. There is insufficient evidence or nexus between the expression of any particular 121P1F1 variant and cancer. The specification does not provide sufficient guidance as to which isolated 121P1F1-related protein (e.g., SEQ ID NO:5) would share the same function or characteristic(s) (i.e., expression profile) as the 121P1F1 protein of SEQ ID NO:2. Neither does the specification provide any working examples of any 121P1F1-related protein (i.e., SEQ ID NO:5) that have the same functional activities or characteristics, i.e., highly expressed in prostate cancer as the 121P1F1 protein. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

In view of the lack of the predictability of the art to which the invention pertains as evidenced by Bost et al and Bendayan M (in addition to the previously cited art of record, e.g., Altwood et al, Skolnick et al, Metzler et al, Lerner R. A., Mikayama et al, Burgess et al, Lazar et al and Ngo et al), the lack of guidance and direction provided by applicant, and the absence of working examples, undue experimentation would be required to practice the claimed transcript variants of SEQ ID NO:1 that encode SEQ ID NO:5 with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed transcript variants and absent working examples providing evidence which is reasonably predictive that the claimed transcript variants of SEQ ID NO:1 have the same functional activities or characteristics of the disclsoed 121P1F1 protein of SEQ ID NO:2, commensurate in scope with the claimed invention.

New Grounds of Rejections

9. Claim 83 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 83 is indefinite in the recitation "which variant is immunoreactive with at least one antibody that specifically binds the amino acid sequence of SEQ ID NO:2". The only reference to a variant in claim 83 is a "transcript variant of a nucleotide sequence comprising SEQ ID NO:1". Thus, it is unclear if the transcript variant of SEQ ID NO:1 is immunoreactive with an antibody that binds the amino acid sequence of SEQ ID NO:2 or if the protein of SEQ ID NO:5 is immunoreactive with an antibody that binds the amino acid sequence of SEQ ID NO:2.

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643